

Certificate of Analysis



Lot status: APPROVED

MODEL RODAC ø55mm Triple Wrapped Sterile Irradiated	PRODUCT CODE	449GLAC1000/21
MEDIA TSA+Lec+T80+Gly+LCT1000	MEDIA COMPOSITION	Tryptone Soy Agar + 0.07% Lecithin + 0.5% Tween80 + 0.2% Glycine + 0.3% Pyruvate + 1000U.I./Lt Lactamator TM
BATCH 30401	STORAGE CONDITIONS	at 2-25°C until expiry date
DATE OF MANUFACTURING 02 Apr 2024	EXPIRY DATE	02 Dec 2024

Medium is prepared utilizing raw materials declared to be TSE-BSE FREE by the manufacturer

CHEMICAL/PHYSICAL TESTS	SPECIFICATION	RESULT
Appearance	light amber coloured, clear to slightly opalescent gel forms in plates	Conforms
pH specification	7.3±0.2	Conforms
Filling media volume	17ml±1ml	Conforms
Packaging	Triple Wrapped Sterile Irradiated (T.W.S.I.)	Conforms
Dose of irradiation	10-25 KGy	Conforms Irradiation certificate Nr:3531890

MICROBIOLOGICAL TEST CONTROLS

- Sterility control**

TESTS	SPECIFICATION	RESULT
32.5±2.5°C aerobic for 120 hours	No growth	Conforms
22.5±2.5°C aerobic for 120 hours		

- Fertility – Growth Promotion Test** according to USP/EP

Control strain	Medium inoculation level	Incubation Conditions	Recovery Specifications	Recovery Results	Cultural Response
<i>E. coli</i> ATCC 8739	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	82,6%	Conforms
<i>P. aeruginosa</i> ATCC 9027	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	94,1%	Conforms
<i>S. aureus</i> ATCC 6538	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	87,8%	Conforms
<i>B. subtilis</i> ATCC 6633	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	106,1%	Conforms
<i>C. albicans</i> ATCC 10231	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	101,8%	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	87,2%	Conforms

- Enzymatic Activity Test**

Control strain	Incubation Conditions	Antibiotics	Response
<i>S. aureus</i> ATCC 6538	24 h at 32.5 ± 2.5°C	Penicillin 10IU	Conforms
		Meropenem 10µg	Conforms
		Cefuroxime 30µg	Conforms
		Ceftazidime 30µg	Conforms
		Cefoxitin 30µg	Conforms

Start analysis	02 Apr 2024	End analysis	22 Apr 2024
Quality Control	Elisabetta Peri	<i>Elisabetta Peri</i>	
Quality Assurance	Alessia Diego	<i>Alessia Diego</i>	

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Customer Name:	CPC Biotech S.r.L.	Processing Facility:	Minerbio	Work Order #	3531890
P.O.#	84064			Sales Order #	3527944
	10-25 kGy	CPCB gamma treatment	Irradiation Date/Time:	5-Apr-24 11:03:19 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	1	PL	2684/20_870/20	Microbiological culture media	WWW0539900781	DDT 84064
		Dose Map	270_CPCB_870/20	Std cycle 15kGy		
102.000	1	PL	2684/20_870/20	Microbiological culture media	WWW0539900782	DDT 84064
		Dose Map	270_CPCB_870/20	Std cycle 15kGy		
103.000	1	PL	2684/20_870/20	Microbiological culture media	WWW0539900783	DDT 84064
		Dose Map	270_CPCB_870/20	Std cycle 15kGy		
104.000	1	PL	2684/20_870/20	Microbiological culture media	WWW0539900784	DDT 84064
		Dose Map	270_CPCB_870/20	Std cycle 15kGy		
	4	PL	Total			

Quality Test Summary

Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail
450.00	Minimum Dose	10.0 kGy	25.0 kGy	15.3 KGY	Pass
450.00	Maximum Dose	10.0 kGy	25.0 kGy	18.5 KGY	Pass

Sterigenics certifies that the materials listed above (as described by the Manufacturer) received the indicated doses within the precision and accuracy of the dosimetry system employed.

Electronically Signed By: VALERIA LOSITO
Reason: Work Order Completions

Date: 8-Apr-24 07:21:46 GMT